

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
NICHOLAS PIRAMAL INDIA LIMITED  
NICHOLAS PIRAMAL TOWER  
PENINSULA CORPORATE PARK  
GANPATRAO KADAM MARG, LOWER PAREL  
MUMBAI (MAHARASHTRA, INDIA 400 013

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

09 FEB 2006

Applicant's or agent's file reference

NPTC 05

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IB05/51103

International filing date (day/month/year)

04 April 2005 (04.04.2005)

Priority date (day/month/year)

04 April 2004 (04.04.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 35/78 and US Cl.: 424/725

Applicant

NICHOLAS PIRAMAL INDIA LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (571) 273-3201

Date of completion of this opinion

25 January 2006 (25.01.2006)

Authorized officer

Michele Flood

MICHELE FLOOD  
PRIMARY EXAMINER

Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB05/51103

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**BEST AVAILABLE COPY**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITYInternational application No.  
PCT/IB05/51103Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 1-17 YES  
Claims NONE NO

Inventive step (IS)

Claims 1-17 YES  
Claims NONE NO

Industrial applicability (IA)

Claims 1-17 YES  
Claims NONE NO

## 2. Citations and explanations:

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method comprising the administration of a standardized extract of *Tinospora cordifolia* in conjunction with either an antibiotic or a steroid for the treatment of renal disorders or nephritic syndrome.

Claims 1-17 meet the criteria set out in PCT Article 33(4), and thus the claims have industrial applicability because the subject matter claimed can be made or used in industry.